

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

John F. SHANLEY *et al.*

Art Unit: 3738

Application No.: **10/729,631**

Examiner: Blanco, Javier G.

Filing Date: December 5, 2003

Attorney Ref. No.: P032 C1

For: EXPANDABLE MEDICAL DELIVERY
DEVICE FOR DELIVERY OF BENEFICIAL
AGENT

REPLY TO NOTICE OF NON-COMPLIANT BRIEF

Mail Stop Appeal Brief - Patents

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

Appellant acknowledges receipt of the Notice of Non-Compliant Brief dated 1 August 2007. Appellant provides herein:

(1) A substitute Summary of the Claimed Invention section, which 'maps' the elements of each of the independent claims, and of the dependent claims argued separately, to the specification by page and line number, and to the drawing figures by reference number when applicable;

(2) A substitute Claims Appendix, in which the words "and" (three occurrences) and "a" (one occurrence) have been deleted in order to accurately present the claims on appeal;

(3) An updated Related Appeals and Interferences section;

(4) An updated Related Proceedings Appendix; and

(5) An updated Real Party in Interest section.

Since the filing of the Reply Brief in this application, appeal was taken to the Board of Patent Appeals and Interferences in a related application, necessitating the submission of items (3) and (4) herein, and ownership of this application has changed, necessitating the submission of item (5). As requested in the Notice, a complete, substitute Appeal Brief is not submitted, but, rather, only those portions requiring correction.

I. REAL PARTY IN INTEREST

The real party in interest is Innovational Holdings, LLC, a corporation of Delaware.

II. RELATED APPEALS AND INTERFERENCES

U.S. Application number 11/273,916, which is related to this application, is under appeal to the Board of Patent Appeals and Interferences; no appeal number has been assigned to that appeal as of the filing date of this Reply, nor has any decision been handed down.

III. STATUS OF CLAIMS

Claims 49-51, 53, 56-62, 74-78, and 81-86 stand finally rejected in the Office Action dated May 16, 2005; Claims 67-73 have been withdrawn; Claims 1-48, 52, 54, 55, 63-66, 79, and 80 have been cancelled. The rejection of each of Claims 49-51, 53, 56-62, 74-78, and 81-86 is the subject of this appeal.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The inventors of the present application have designed a novel reservoir-based drug-delivery stent technology with individual drug depots for loading one or more drugs and protective carriers, referred to as the Conor stent. The Conor stent design incorporates hundreds of drug-delivery reservoirs, filled with a matrix of polymer and a drug. The reservoirs are filled in a plurality of filling and evaporating steps to form independently programmable drug depots.

The Conor depot technology addresses the limitations of current drug-eluting stents. Unique to Conor's technology is the ability to choose drugs and carrier materials which provide programmed release kinetics without the limitations of materials suitable for coatings. Conor's

drug-delivery system is also the first system to allow independent drug release kinetics for multiple drugs.

The present application describes expandable medical devices, such as stents, embodying reservoirs, openings, or depots of beneficial agents which are used to control release of drugs from the reservoirs, openings, or depots in the expandable devices, and methods of making such devices. Through careful configuration of the device, the reservoirs, openings, or depots are substantially non-deforming during expansion and contraction of the device, which protects the beneficial agent(s) against fracture, extrusion from the reservoirs, openings, or depots, deformation, and associated detrimental effects on drug delivery.

Claim 49: An expandable medical device [10, Fig. 1, page 10, lines 8-10] includes a substantially cylindrical expandable device body [12, Fig. 1, page 10, lines 10-11] including and formed by a plurality of struts [18, Figs. 1 and 2, page 10, lines 17-19] with a plurality of openings [24, 26, Fig. 1, page 12, lines 22-26; 24', 26', Fig. 3, page 15, lines 20-23] formed in the plurality of struts [page 10, lines 10-11 and 17-21]. Inside the openings, a plurality of layers [50, Figs. 9, 10, 11A, page 18, lines 4-5] of beneficial agent [36, Figs. 6-8, page 17, lines 15-23, and page 18, lines 4-5] are provided. The plurality of beneficial agent layers include a first active agent arranged for delivery according to a first release profile and a second active agent arranged for delivery according to a second release profile, wherein the first and second release profiles are different [page 23, line 20 to page 24, line 20]. A barrier layer [52, Figs. 10, 11A, 12, page 22, line 8 to page 23, line 2] is adjacent a luminal side of the device body [page 22, lines 22-24] which blocks or retards delivery of the first and second active agents to the luminal side of the device body through the openings (page 14, lines 4-15 *et seq*; page 17, lines 15-16; page 18, lines 4-27).

Claim 59: An expandable medical device [10, Fig. 1, page 10, lines 8-10] includes a substantially cylindrical expandable medical device body [12, Fig. 1, page 10, lines 10-11] formed of a plurality of struts [18, Figs. 1 and 2, page 10, lines 17-19]; a plurality of openings [24, 26, Fig. 1, page 12, lines 22-26; 24', 26', Fig. 3, page 15, lines 20-23] in the plurality of struts [page 10, lines 10-11 and 17-21]; and

a plurality of beneficial agent layers [50, Figs. 9, 10, 11A, page 18, lines 4-5; 36, Figs. 6-8, page 17, lines 15-23, and page 18, lines 4-5] formed in the openings, wherein the plurality of beneficial agent layers include a first active agent layer arranged for delivery primarily to a first side of the device body [56, Fig. 13, page 24, lines 17-18] and a second active agent layer arranged for delivery to the first side of the device body [page 23, line 20 to page 24, line 20].

Claim 74: An expandable medical device [10, Fig. 1, page 10, lines 8-10] includes a substantially cylindrical expandable medical device body [12, Fig. 1, page 10, lines 10-11] formed of a plurality of struts [18, Figs. 1 and 2, page 10, lines 17-19];

a plurality of openings [24, 26, Fig. 1, page 12, lines 22-26; 24', 26', Fig. 3, page 15, lines 20-23] in the plurality of struts [page 10, lines 10-11 and 17-21];

a first active agent contained in the plurality of openings and arranged for delivery according to a first release profile [page 23, line 20 to page 24, line 20];

a second active agent contained in the plurality of openings and arranged for delivery according to a second release profile, wherein the first and second release profiles are different [page 23, line 20 to page 24, line 20]; and

wherein the first and second active agents are arranged to be delivered to a first side [56, Fig. 13, page 24, lines 17-18] of the device body [page 23, line 20 to page 24, line 20].

In the device, the first and second active agents can be arranged to be delivered to a mural side [page 23, line 20 to page 24, line 20] of the device body [Figs. 10, 11A, 12, *id.*]

In the device, the first active agents can be an anti-proliferative [page 14, line 18], and the second active agent can be an anti-inflammatory [page 14, line 19].

In the device, the barrier layer can be formed in the openings [page 22, lines 8-10].

In the device, the first and second release profiles can be designed to coordinate with cellular biochemical processes [page 24, lines 3-13].

In the device, the first and second active agents layers can include the same active agent [*passim*; see, *e.g.*, page 22, lines 8-24] in different concentrations [page 24, lines 14-20].

In the device, the two active agent release profiles can have different durations [page 21, lines 1-19].

In the device, the plurality of openings can be laser drilled through holes [page 12, lines 22-24] and the device body can be a one-piece cylindrical structure [page 11, line 21 to page 12, line 6; Fig. 1].

Respectfully submitted,

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CLAIMS APPENDIX

49. An expandable medical device comprising:
- a substantially cylindrical expandable medical device body formed of a plurality of struts;
 - a plurality of openings in the plurality of struts;
 - a plurality of beneficial agent layers formed in the openings, wherein the plurality of beneficial agent layers include a first active agent arranged for delivery according to a first release profile and a second active agent arranged for delivery according to a second release profile, wherein the first and second release profiles are different; and
 - a barrier layer adjacent a luminal side of the device body which blocks or retards delivery of the first and second active agents to the luminal side of the device body through the openings.
50. The device of Claim 49, wherein the first and second active agents are arranged to be delivered to a mural side of the device body.
51. The device of Claim 50, wherein the first active agent is an anti-proliferative and the second active agent is an anti-inflammatory.
53. The device of Claim 50, wherein the barrier layer is formed within the openings.

56. The device of Claim 49, wherein the first and second release profiles are designed to coordinate with cellular biochemical processes.
57. The device of Claim 49, wherein the first and second release profiles are of different duration.
58. The device of Claim 49, wherein the first release profile includes programmable bursts.
59. An expandable medical device comprising:
a substantially cylindrical expandable medical device body formed of a plurality of struts;
a plurality of openings in the plurality of struts; and
a plurality of beneficial agent layers formed in the openings, wherein the plurality of beneficial agent layers include a first active agent layer arranged for delivery primarily to a first side of the device body and a second active agent layer arranged for delivery to the first side of the device body.
60. The device of Claim 59, wherein the first and second active agent layers include different active agents.
61. The device of Claim 59, wherein the first and second active agent layers include the same active agent.

62. The device of Claim 59, wherein the first and second active agent layers include the same active agent in different concentrations.

74. An expandable medical device comprising:

a substantially cylindrical expandable medical device body formed of a plurality of struts;
a plurality of openings in the plurality of struts;
a first active agent contained in the plurality of openings and arranged for delivery according to a first release profile;

a second active agent contained in the plurality of openings and arranged for delivery according to a second release profile, wherein the first and second release profiles are different;
and

wherein the first and second active agents are arranged to be delivered to a first side of the device body.

75. The device of Claim 74, wherein the first and second active agents are arranged to be delivered to a mural side of the device body.

76. The device of Claim 75, wherein the first active agent is an anti-proliferative and the second active agent is an anti-inflammatory.

77. The device of Claim 75, further comprising a barrier layer adjacent a luminal side of the device body which blocks or retards delivery of the first and second active agents to the luminal side of the device body through the openings.

78. The device of Claim 77, wherein the barrier layer is formed within the openings.

81. The device of Claim 74, wherein the first and second release profiles are designed to coordinate with cellular biochemical processes.

82. The device of Claim 74, wherein the first and second release profiles are of different duration.

83. The device of Claim 74, wherein the first release profile includes programmable bursts.

84. The device of Claim 49, wherein the plurality of openings are laser drilled through holes and the device body is a one piece cylindrical structure.

85. The device of Claim 59, wherein the plurality of openings are laser drilled through holes and the device body is a one piece cylindrical structure.

86. The device of Claim 74, wherein the plurality of openings are laser drilled through holes and the device body is a one piece cylindrical structure.

RELATED PROCEEDINGS APPENDIX

In the appeal in U.S. Application number 11/273,916, which is related to this application, no decision has been handed down.